Section 5: 510(k) Summary

K071047

JUN - 8 2007

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 PHONE (949) 297-7000 FAX (949) 297-7001
Official Correspondent:	James Cronin, Vice President, Regulatory Affairs
Company Contact for this Submission:	Marguerite Thomlinson, Manager, Regulatory Affairs
Date Summary Prepared:	April 12, 2007
Trade Name:	Masimo Patient Safety Net
Common Name:	System, Network and Communication, Physiological Monitors
Device Class:	Class II
Product Code:	MSX
Classification Name:	System, Network and Communication, Physiological Monitors
Substantially Equivalent Devices:	Bernoulli Management System 510(k) Number – K061932

Description of Masimo Patient Safety Net

The Masimo Patient Safety Net (PSN) is a supplemental alarm system for physiological monitoring devices. It is not intended to replace any part of the patient monitoring procedures already existing for the patient monitoring devices.

The PSN communicates with multiple patient monitoring devices and distributes physiological monitoring information remotely. Skilled clinicians remotely receive wireless transmission of patient physiological monitoring information, from patient monitoring device(s) to their pagers. The transmitted information includes alarm information and physiological parameters.

Intended use/ Indications for Use

The Masimo Patient Safety Net (PSN) is intended to be used as a supplemental alarm system, communicating with multiple patient monitoring devices. The PSN provides secondary display of physiological monitoring parameters. It enables the viewing and monitoring of patient physiological conditions. The PSN is used in hospitals or hospital-type environments.

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Technology

The Masimo Patient Safety Net (PSN) includes standard telecommunication and IT hardware. Masimo develops the application software which is used on the system server and PC computer (central monitoring station).

The PSN functions and transmits data similarly to the predicate device. The PSN and the predicate device use similar data transmission and communication technologies.

Test Summary

The Masimo Patient Safety Net (PSN) complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the PSN:

- Risk Analysis
- Design Reviews
- Component Level Testing
- System Level Testing
- Performance Testing
- Safety Testing
- Environmental Testing

Conclusions

The information in this 510(k) submission demonstrates that the Masimo Patient Safety Net is substantially equivalent to the predicate device as a supplementary alarm system, with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2007

Masimo Corporation
c/o Marguerite Thomlinson
Manager, Regulatory Affairs
40 Parker
Irvine, California 92618

Re: K071047
Masimo Patient Safety Net
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: April 12, 2007
Received: April 13, 2007

Dear Ms. Thomlinson:

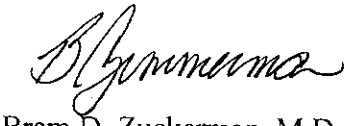
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use

510(k) Number (if known): K071047

Device Name: Masimo Patient Safety Net

Indications For Use:

The Masimo Patient Safety Net (PSN) is intended to be used as a supplemental alarm system, communicating with multiple patient monitoring devices. The PSN provides secondary display of physiological monitoring parameters. It enables the viewing and monitoring of patient physiological conditions. The PSN is used in hospitals or hospital-type environments.

Prescription Use ___X_____ AND/OR Over-The-Counter Use

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071047